

Module 9c: Other Compliance/Noncompliance—SSOPs

Let's turn our attention to SSOPs. In January 1997 SSOPs were required in all official establishments. By now, you have had the opportunity to perform in-plant SSOP verification, documentation and enforcement activities. Until HACCP is implemented, you will use FSIS Directive 11,100.3 and the same PBIS terms.

When HACCP is implemented in the plant, you'll perform your pre-operational and operational sanitation inspection the same way. Using the review and observation or recordkeeping procedure, you'll still be responsible for verifying that the plant is implementing their SSOP and monitoring that implementation. You'll still determine if the establishment is routinely evaluating the effectiveness of their SSOP and that they're taking corrective actions when needed.

Not everything will remain the same however. They'll be two changes in HACCP plants. First, you will follow a new directive. Part Three of FSIS Directive 5000.1 provides instructions on verification, documentation, and enforcement activities related to the SSOP. Second, you'll use the new PBIS procedures and terminology in FSIS Directive 5400.5.

Let's review the changes in PBIS. Under the old PBIS system, "evaluation" was used to determine if the plan met the regulatory requirements. "Basic compliance/noncompliance" is the new term for determining if the plan met the regulatory requirements. "Verification" is called "Other compliance/noncompliance" in HACCP establishments. "Tasks" described the work performed by inspection. "Procedure" describes that work now. The Deficiency Classification Guide is replaced by the Noncompliance Guide. Deficiencies were documented on a PDR. Noncompliance will be documented on an NR. A complete list that compares the old and new terms as they apply to SSOPs is included in your notebook.

You learned to use an SSOP process flow diagram during your Pre-HACCP training. A similar diagram was developed to guide you through the regulatory process for HACCP and SSOP-related activities in a HACCP plant.

Blocks 1 through 6 address the basic regulatory requirements. You heard about these requirements earlier.

"Other" regulatory requirements begin at Block 7, entitled "FSIS performs other procedures". For SSOP-related activities "other" means ISP procedures 01B01 and 01B02 for pre-operational sanitation and 01C01 and 01C02 for operational sanitation.

As before, the recordkeeping procedure is for reviewing the daily documentation regarding the implementation of the SSOP procedures and the corrective actions taken.

You will also perform a review and observation procedure. This is the same as the old "hands-on" verification task. Performing the procedure is just like performing the task. That is, you'll conduct an organoleptic examination of the facilities, utensils, and equipment. You'll observe as plant employees monitor both pre-op and operational

sanitation procedures and take corrective actions. You'll look at records. It is the review and observation procedure that provides you the opportunity to compare inspection findings with plant records.

Both the recordkeeping and review and observation procedures allow you to verify four plant requirements for the SSOP. These four requirements are implementation, effectiveness (monitoring), corrective actions, and records.

First, you determine that the SSOP is being implemented. The establishment should conduct pre-operational procedures and procedures during the operation to monitor implementation of their SSOP.

Second, you determine that the plant is taking appropriate corrective actions. Corrective actions must properly dispose of contaminated product, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration. Corrective actions even includes reevaluation and modification of the SSOP when necessary.

The third thing you determine when you perform the SSOP procedures is that the plant ensures that it remains effective. They must routinely evaluate the effectiveness of the SSOP in preventing direct product contamination or adulteration. They should revise the SSOP to reflect changes in facilities, equipment, utensils, operations, or personnel.

Lastly, you determine that the plant is keeping records. Records must be initialed and dated by the responsible establishment employee identified in the SSOP. In cases where records are kept on company computers, the establishment must ensure data integrity. Controls like individual digital signatures or identification passwords prevent tampering with data. Of course, SSOP records still must be kept on-site for 48 hours. After that they can be stored either on-site or off-site, but they must be kept at least six months. During that six months, records must be available to FSIS employees within 24 hours of request.

Another thing to be aware of when checking records is evidence of misrepresentation or falsification. Anytime you suspect this illegal activity, you should take actions necessary to protect the public health. Then, you should call the District Office. The District Manager will enlist the help of the District Enforcement Operations official.

Moving to Block 8 of the diagram: "Is noncompliance found?" Use what's known for a fact and what's reasonable to assume to determine if noncompliance exists. Make sure you've given the establishment the opportunity to implement their SSOP procedures before you decide. For example, imagine you're performing the review and observation procedure for operational sanitation. You notice meat on the floor - not an excessive amount. Let's assume the establishment's SSOP indicates that the floor supervisor will monitor meat on the floor. Records indicate he has monitored at the correct frequency during the shift, but it's not time for the next check yet. Here, it's reasonable for you to assume that the floor supervisor is following the SSOP. Part of the performance of this inspection procedure might in fact include returning to the area to observe the next monitoring activity by the plant and/or the records. If the floor supervisor returns,

observe his actions. Does he monitor the area, make corrections, and record the findings? If so, the SSOP is being implemented. There's compliance.

Noncompliance exists when the establishment isn't implementing their SSOP or when the SSOP doesn't prevent direct contamination or adulteration of product. In our example, if the floor supervisor didn't monitor the area, correct the problem, or document findings noncompliance exists.

Block 9 in the regulatory process model indicates that you must decide whether there's a system failure. For SSOPs, when there's "other" requirements noncompliance, ask yourself a couple of questions. First, was adulterated product produced? If there's adulterated or contaminated product, there's either a design failure or an execution failure of the SSOP. But it's a failure of the SSOP at this point, not a system failure.

The second question, then, is, "Do the noncompliances have the same root cause?" That is, are there the same and/or related noncompliances due to the negligence, ineffective method, or incomplete execution by the plant? Look at previous NRs and PDRs. Analyze the trend indicators. Your professional analysis is critical. There still isn't a magic number to decide when a systems failure exists. The NRs and PDRs should document ongoing failures of the plant's maintenance or implementation of the SSOP and/or execution of effective immediate and further planned actions to bring themselves back in to regulatory compliance. You will want to be certain that your documentation made the linkage to the previous noncompliance. If you are able to determine the linkage exists, and the documentation supports it, then you have a systems failure.

Lastly, you should ask if the establishment has met the Basic regulatory requirements. That is, if the establishment is not implementing some or all of their SSOP procedures, then they have not met the Basic regulatory requirements. For example, if an establishment doesn't maintain any records, or if it doesn't monitor the SSOP at all then the establishment has not met the regulatory requirements. We consider this an inadequate system because the establishment has not met the Basic regulatory requirements and therefore we are not able to determine that the establishment is not producing adulterated product. This would be documented under the Basic procedure code 01A01.

If you decide there is a system failure, follow the flow diagram to Block 11. Withhold inspection and advise plant management. Notify the District Office of withholding action resulting from a system failure. The District Office will provide instructions about further inspection actions. Document the noncompliance on an NR.

If you decide there isn't a system failure, proceed from Block 9 to Block 10. Take official control action for SSOP failures. Retain affected product or reject departments to prevent further adulteration or contamination of product. Remember that official control action should continue until the establishment takes appropriate corrective action. Complete an NR. Give a copy to plant management.

Anytime noncompliance is found document your findings. You must select a trend indicator on the NR. There are four SSOP trend indicators from which to choose: implementation, monitoring, corrective actions, and recordkeeping.

Due to the fact so many things are encompassed in implementation, use the implementation trend indicator when more than one trend indicator fits. For example, if the floor supervisor hadn't taken corrective action when he returned to monitor the area, and he hadn't completed a log entry, two trend indicators would apply - corrective action and recordkeeping. Never use more than one trend indicator for each procedure, even if they seem equally appropriate. When more than one trend indicator applies, mark implementation.

The monitoring noncompliance trend indicator is used when the plant isn't **monitoring their pre-operational and operational sanitation procedures daily.**

The corrective actions trend indicator is used when appropriate corrective action isn't taken. Corrective action requires that the plant properly disposes of contaminated or adulterated product, returns to sanitary conditions, and prevents recurrence of the problem.

Recordkeeping is marked when you find noncompliance with the recordkeeping requirements mentioned earlier.

Not every noncompliance you observe while performing an SSOP procedure will represent an SSOP failure. What about noncompliance that doesn't result in direct contamination or adulteration of product, therefore, doesn't come under the SSOP? You must document it, too. For example, if you're performing pre-op sanitation inspection and you observe a four-inch glob of fat on the leg of the final inspection stand, you've identified a sanitation noncompliance. The noncompliance, in your judgment, won't result in direct product contamination. The SSOP hasn't failed because there isn't direct product contamination. There's noncompliance with the regulation that requires removal of residues from previous days' operations, though. You must document the noncompliance on an NR. Although you were performing the SSOP procedure when the noncompliance was found, since the noncompliance isn't an SSOP failure, you would document this as an unscheduled 06D01 procedure. You would mark one of the facilities trend indicators, specifically, mark the "product based" trend indicator. If no other noncompliance was found while performing this SSOP procedure, you would document the SSOP procedure as performed on the Procedure Schedule.

Details on how to perform SSOP procedures in a HACCP plant are in FSIS Directive 5000.1. A copy is in your notebook.